FDA 510(k) Premarket Notification

K053188 REPROCESSED BALOON INFLATION DEVICE

CLEARED

May 4, 2006
170 days to decision

K053188 · Product code: **NKU** · Cardiovascular
Source: https://www.510kdatabase.net/k053188/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic, Balloon Inflation, Reprocessed (NKU)
Date received	Nov 15, 2005
Decision date	May 4, 2006
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sterilmed, Inc.**
Location	Plymouth, MN, US
Contact	BRUCE R LESTER
510(k) history	64 submissions · 64 cleared · 2001-2024